UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

DK

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/072,994	05/05/98	COTTAREL G	MIV-032.02

HM12/1207

FOLEY HOAG & ELIOTT
ONE POST OFFICE SQUARE
BOSTON MA 02109-2170

EXAMINER	
PAK, M	
ART UNIT	**PAPER NUMBER**
1646	12

DATE MAILED: 12/07/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/072,994	Applicant(s) Cottarel et al.
	Examiner Michael Pak	Group Art Unit 1646

☒ Responsive to communication(s) filed on *Aug 26, 1999* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-40* is/are pending in the application.

Of the above, claim(s) *1-13 and 23-36* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *14-22 and 37-40* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The preliminary amendments filed on 26 August 1999, Paper No. 11, has been entered.

Election/Restriction

2. Applicant's election with traverse of Group III, claims 14-22, in Paper No. 11 is acknowledged. The traversal is on the ground(s) that examination of group IV would not present a serious search burden. This is not found persuasive because as discussed in the last office action, the groups are classified separately. The requirement is still deemed proper and is therefore made final.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

4. The information disclosure statement filed 24 February 1999 (Paper No. 8) fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification Objections

5. The specification is objected to because of the following informalities. Appropriate correction is required.

The specification are objected to because they do not comply with 37 C.F.R. 1.821 (d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specifications wherever a reference is made to that sequence. For example, the sequences on pages 35-38 should be referenced with the appropriate SEQ ID NO:. See M.P.E.P. 2422.04. The specification should be reexamined to find any sequences without an appropriate SEQ ID NO:.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using

> it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 14-22 and 37-40 are rejected under 35 U.S.C. § 112, first paragraph. The specification is enabling for: a DNA of SEQ ID NO:13 encoding a functional CAK polypeptide of SEQ ID NO:14; a DNA sequence that deviates from SEQ ID NO:13 due to degeneracy in the genetic code and encodes a CAK polypeptide of SEQ ID NO:14 which is functional. The specification does not reasonably provide the full scope of enablement for: a) a DNA encoding all variants and fragments of the CAK polypeptide which deviate to such an extent from the disclosed sequence as to be not functional; b) any DNA wherein the encoded CAK polypeptide functions in one of either role of an agonist or an antagonist of cell cycle regulation of a Candida cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention in a manner which is commensurate in scope with the claims.

a) The claims encompass DNA encoding any CAK polypeptide capable of functioning as a CAK polypeptide including sequence variants and fragments of the disclosed polypeptide. Since the specific definition of a CAK polypeptide is not disclosed, the claims read on any CAK polypeptides and variants. The specification on page 6 describes CAK polypeptide and Examples

in the specification provides an example of the cloning of the TYP1 DNA of SEQ ID NO:1. However, no working example nor guidance is provided concerning a functional CAK polypeptide with the claim limitations of "at least 75% homologous to an amino acid sequence represented in SEQ ID NO:14." It is not known in the art how to make and use a DNA encoding CAK polypeptide, where the polypeptide is 75% homologous with a DNA sequence. Without such guidance the experimentation necessary to make and use a DNA encoding CAK polypeptide which is 75% homologous with SEQ ID NO:14 is unpredictable.

b) The claims encompass DNA encoding any polypeptide capable of functioning as a CAK polypeptide including sequence variants and fragments of the disclosed polypeptide. Since the specific definition of a CAK polypeptide is not disclosed, the claims read on any CAK polypeptides and variants. The specification on page 6 describes CAK polypeptide and Examples in the specification provides an example of the cloning of the TYP1 DNA and the functional characterization of TYP1. However, sequence similarity alone without function is insufficient to support claims to polypeptides other than the disclosed sequence because the genus includes inactive proteins. Although some CAK polypeptide fragments and variants are able to function as a kinase, the claims encompass fragments or fragments with substitutions which are not functional polypeptide and the

specification does not provide enabling disclosure for the non-functional polypeptides. Without such disclosure, the experimentation necessary to determine how to make and use the nonfunctional fragments and variants is unpredictable. For example, any CAK polypeptide fragment which does not include the kinase domain or deviates in structure from SEQ ID NO:14 to such an extent as not to function as a kinase cannot be used to practice this invention. No working example using variants or fragments which would result in a functional CAK polypeptide is disclosed. No guidance is provided which would allow one skilled in the art to make substitutions or use any fragments of SEQ ID NO: 14 and retain a functional protein. It should be noted that discussion on page 21 of the specification is restricted to conservative substitutions and no discussion is provided regarding the rest of the non-functional fragments and variants encompassed by the claims. One skilled in the art could not reasonably make and use the fragments and variants which do not have CAK polypeptide function. Without such guidance, the experimentation necessary to determine all the possible variations of substitutions, modifications, or additions necessary to make a DNA encoding a functional CAK polypeptide is unpredictable.

c) The limitation of claim 15 requires an assay to determine an

agonist or an antagonist of cell cycle regulation of a Candida cell. Although assays are available to one skilled in the art to study cell cycle regulation in yeasts such as S. pombe or S. cerevisiae, the specification does not provide guidance nor a working example of an assay which utilizes Candida cell. Without such guidance one skilled in the art cannot make and use the invention with the claim limitation for determining an agonist or an antagonist of cell cycle regulation of a Candida cell. One skilled in the art could not reasonably make and use the nucleic acid encoding CAK polypeptide with the functional limitation of either role of an agonist or an antagonist of cell cycle regulation of a Candida cell. Without such guidance, the experimentation necessary to determine such a function for a DNA encoding a functional CAK polypeptide is unpredictable.

In view of the breadth of the claims and the large extent and unpredictable nature of the experimentation which would be involved due to discussions in a-c listed immediately above, one skilled in the art could not make the full scope of the invention as claimed without undue experimentation.

8. Claims 14-22 and 37-40 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 38 recite "... 75% homologous to an amino acid sequence represented in SEQ ID NO:14." "Homologous", as the term is conventionally used in the art, is a evolutionary relationship of sequence comparisons whereas sequence "identity" or "similarity" refers to the structural features of the sequences. The claim is therefore unclear as to what is the evolutionary significance and relationship between the CAK polypeptide and the SEQ ID NO:14. Claims 15-22 are dependent on claim 14.

Claim 37 is indefinite for recitation of ▒stringent conditions▒ which is a relative term and it is not clear whether the condition is high, moderate, or low stringency condition for hybridization. Claims 38-40 are dependent on claim 37.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
6 November 1999